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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,606	02/27/2004	Anthony Malone	12013/50501	9058
23838	7590	06/26/2008		
KENYON & KENYON LLP 1500 K STREET N.W. SUITE 700 WASHINGTON, DC 20005			EXAMINER SELLMAN, CACHET I	
			ART UNIT 1792	PAPER NUMBER
			MAIL DATE 06/26/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/789,606

Applicant(s)

MALONE

Examiner

CACHET I. SELLMAN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-15 and 17-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-15 and 17-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgement is made of the amendment filed by the applicant on 12/27/2007, in which claims 1, 3, 5, 6-8, 14-15, 17-19 were amended, claims 2, 4 and 16 were cancelled and claim 25 was added. Claims 1,3,5-15 and 17-25 are currently pending in U.S. Application Serial No. 10/789606.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 3, 5, -13, 15, 17- 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Talton in view of Shalaby et al.

Talton teaches a method for applying a thin coating to surfaces of a substrate such as biomedical devices, which improve surface interactions in gaseous, liquid or biological environments [0003]. The devices are coated using a pulsed laser, where a target material is ablated using a laser to form an ablated target particulate material and the particulate material is directed towards the substrate using a gas flow to coat the substrate surface (abstract and 0047). The target material can include active materials such as biologically active coatings i.e. antigens, nucleic acids, proteins or pharmaceuticals [0035-36, 0047 and 0060]. The target can comprise a target solution of the polymer and drug dissolved in a solvent [0047].

Talton fails to teach mixing the polymer and drug solution during the coating step. However, it was well known in the art at the time the invention was made to mix the polymer and drug as well as filter the solution as shown by Shalaby et al. Shalaby et al.

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teaches a process for coating stents with a drug polymer solution. The drug and polymer solution is mixed to insure there is a uniform mixture and coating applied to the medical device as well as filtered to insure that no unmixed drug is left in the solution.

Shalaby et al. does not teach mixing the solution during coating. However, it would have been obvious to one having ordinary skill in the art to maintain the mixing step during the coating process in order to provide a uniform coating to the medical device by supplying a uniform coating solution which Shalaby et al. teaches is achieved by mixing the coating solution.

It is well known to use a stirrer or sonicator when mixing to make sure there is complete mixing. As shown in WO/1992/001443, a stirrer is used to mix the polymer and drug to form a uniform solution or by sonicating US 6183781 (col. 5, 40-50).

The solvent is removed by pumping from the evaporation chamber through the exhaust duct [0048] as required by **claims 8 and 20**. The drug and polymer is transported to the target using a gas flow [0044] as required by **claim 9**. The gas is an inert gas [0041] as required by **claim 10**. The device being coated can be a stent [0058] as required by **claims 11 and 21**. The can be a UV laser and is pulsed [0056] as required by **claims 12-13**.

3. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Talton et al. in view of Shalaby as applied above, in further view of view of Mori (JP 10074985).

Talton in view of Shalaby fails to teach using second laser to ablate a second target so the second target is applied to the medical device as required by **claim 14**.

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However, Talton teaches that different combinations of polymers and drugs and compositions can be applied to the medical device.

Mori teaches tht different targets can be ablated or vaporized by using a laser with a mirror so different targets can be disposed onto a substrate oppositely. Mori teaches that a plume of the target is formed and is deposited onto the substrate. It would have been obvious to one having ordinary skill in the art to modify the process of Talton to include the use of a mirror in laser device in order to dispose another target in order to customize the medical device depending on its intended use especially since Talton teaches the use of multiple drug/polymer compositions.

Conclusion

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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4. Applicant's arguments with respect to claims 1, 15 and 25 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CACHET I. SELLMAN whose telephone number is (571)272-0691. The examiner can normally be reached on Monday through Friday, 7:00 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cachet I Sellman/
Examiner
Art Unit 1792

/C. I. S./
Examiner, Art Unit 1792

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/William Phillip Fletcher III/
for Timothy H. Meeks, SPE of Art Unit 1792/1700